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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/486,069 | 06/07/1995 | DEAN ENGELHARDT | ENZ-5(D8)(C2 | 6278 |

28171 7590 05/19/2005

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NEW YORK, NY 10022

EXAMINER

MARSCHER, ARDIN H

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------------|--|
| Office Action Summary | Application No. 08/486,069 | Applicant(s) ENGELHARDT ET AL. | |
| | Examiner Ardin Marschel | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on (see attachment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) (see attachment) is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) (see attachment) is/are allowed.
- 6) ☒ Claim(s) (see attachment) is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Item # 1) on the enclosed PTO Form 326: 12/31/03, 5/21/04, 7/13/04, 9/14/04, 9/28/04, and 1/21/05

Item # 4) on the enclosed PTO Form 326: Claims 569-571, 573-575, 577, 582-589, 592-594, 597-600, 602-604, 607, 608, 610-612, 614-624, 634, 635, 637, 638, 641, 642, 646, 648-651, 656-661, 667, 670, 707-714, 716, 717, 719-723, 725-727, 729, 734-747, 749-752, 754-756, 759, 760, 762-764, 766-776, 786, 787, 789, 790, 793, 794, 796, 797, 800-803, 808-813, 819, 822, 859-866, 868, 869, 871-875, 877-879, 881, 886-899, 901-904, 906-908, 911, 912, 914-916, 918-928, 938, 939, 941, 942, 945-947, 949, 952-955, 960-965, 971, 974, 1011-1018, 1020, 1021, 1023-1027, 1029-1031, 1033, 1038-1051, 1053-1056, 1058-1060, 1063, 1064, 1066-1068, 1070-1080, 1090, 1091, 1093, 1094, 1097-1099, 1101, 1104-1107, 1112-1117, 1123, 1126, 1163-1170, 1172, 1173, 1175-1179, 1181-1183, 1185, 1190-1200, 1204, 1208, 1209, 1212-1216, 1218-1244, 1248, 1249, 1253, 1255-1258, 1263-1270, 1272, 1275, 1278-1294, 1296, 1297, 1411-1487, 1490, 1491, 1493-1516, 1518, 1520-1525, 1527, 1530-1539, 1541, 1544-1568, 1570-1581, 1700-1724, 1727-1757, 1760-1773, and 1775-1796 are pending in the application.

Item # 5) on the enclosed PTO Form 326: Claims 569-571, 573-575, 577, 582-589, 592-594, 597-600, 602-604, 607, 608, 610-612, 614-624, 634, 635, 637, 638, 641, 642, 646, 648-651, 656-661, 667, 670, 707-714, 716, 717, 719-723, 725-727, 729, 734-747, 749-752, 754-756, 759, 760, 762-764, 766-776, 786, 787, 789, 790, 793, 794, 796, 797, 800-803, 808-813, 819, 822, 859-866, 868, 869, 871-875, 877-879, 881, 886-899,

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901-904, 906-908, 911, 912, 914-916, 918-928, 938, 939, 941, 942, 945-947, 949, 952-955, 960-965, 971, 974, 1011-1018, 1020, 1021, 1023-1027, 1029-1031, 1033, 1038-1051, 1053-1056, 1058-1060, 1063, 1064, 1066-1068, 1070-1080, 1090, 1091, 1093, 1094, 1097-1099, 1101, 1104-1107, 1112-1117, 1123, 1126, 1163-1170, 1172, 1173, 1175-1179, 1181-1183, 1185, 1190-1200, 1204, 1208, 1209, 1212-1216, 1218-1244, 1248, 1249, 1253, 1255-1258, 1263-1270, 1272, 1275, 1278-1294, 1296, 1297, 1411-1435, 1440, 1445-1487, 1490, 1491, 1493-1499, 1504-1516, 1518, 1520-1525, 1527, 1530-1539, 1541, 1544-1568, 1570-1581, 1700-1722, 1727-1739, 1742-1757, 1760-1773, and 1775-1795 are allowed.

Item # 6) on the enclosed PTO Form 326: Claims 1436-1439, 1441-1444, 1500-1503, 1723, 1724, 1740, 1741, and 1796 are rejected.

Applicants' arguments; filed 12/31/03, 5/21/04, 7/13/04, 9/14/04, 9/28/04, and 1/21/05; have been fully considered but they are not deemed to be persuasive.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

MISSING INTERVIEW SUMMARY

Applicants are reminded of the requirement to submit an Interview Summary for Interviewed held in the instant application. It is noted that applicants have failed to supply an Interview Summary for the Interview held on 4/1/04.

NEW MATTER

Claims 1500-1503, 1723, 1724, 1740, 1741, and 1796 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The NEW MATTER rejection directed to the chemical linkages specified as an olefinic bond, various amines, etc. to other nucleotide or nucleotide analog structures other than attaching a Sig moiety to a Base moiety is maintained from the previous office action, mailed 7/1/03. Applicants argued that they have amended the claims cited in said previous office action to limit the claims cited therein regarding this issue to only such chemical linkages between Sig and Base moieties. Consideration of the presently pending claims reveals that claims 1500-1503 have not been amended to require such limitation and still contain the above indicated NEW MATTER.

The NEW MATTER rejection directed to NEW MATTER limitations "different or same indicator molecules" set forth in the previous Office action, mailed 7/1/03, is maintained and reiterated from said Office action. Applicants argued in their REMARKS, filed 12/31/03, on page 10 therein that firstly sections II(B) and II(C) provide support as filed for these limitations. Consideration of said sections II(B) and II(C) reveals that applicants have not indicated written support for these limitations as filed but rather argue that this issue has not been raised previously regarding claim

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amending for at least four years. This timing issue is regretted, but does not negate this rejection which is based on a lack of written basis for these limitations as originally filed.

Applicants also argue regarding related claims as allowed etc. In response, each application is considered on its own merits notwithstanding what occurs in other applications. Applicants then argue that different non-radioactive indicators are cited such as fluorescein, rhodamine and dansyl. In response the listing of such different indicators are reasonably interpreted as options for the Sig moiety in the claimed invention but not that this appreciates the comparative same or different presence of "multiple" Sig moieties in any of the instantly claimed methods wherein such indicator options are present as utilized together within step(s) of the methods as claimed thus failing to overcome this rejection. Applicants then point to In re Alton for support.

Consideration of In re Alton reveals that the fact pattern therein discussed is directed to whether there is written support for particular human gamma interferon types (e.g., IFN-c) given various citations of sequence alternatives modifying a parent IFN sequence.

The In re Alton decision indicates that given the citation of various sequence options that the described sequence options may be separated supportive of IFN embodiments, one of which overcomes a NEW MATTER rejection therein. This is a different and distinct fact pattern from the instant disclosure in that no such separation of alternatives is disclosed as filed in order to give written support for specific embodiments therein.

Also, the decision of In re Alton is based at least in part to a Declaration filed to indicate the facts as would be known to someone of ordinary skill in the art given disclosed IFN sequence alternatives. It is acknowledged that a Declaration of Dr. James J. Donegan

has been filed on 9/14/04, as to what someone would have known from the instantly originally filed disclosure. The only portion of this Declaration which discusses sequencing methodology is in the bridging sentence between pages 6 and 7. This sentence sets forth an opinion without factual support for the practice of different fluorescent labels being utilized in nucleic acid sequencing. Such an opinion Declaration was discussed in *In re Alton* as being non-persuasive. Thus, in summary, the *In re Alton* decision is moot regarding this rejection. Applicants then argue that different colored fluorescent indicators are disclosed as filed regarding cited passages directed to karyotyping wherein different chromosomes are labeled with different colors. This disclosure is acknowledged as being persuasive regarding instant claims directed to such karyotyping. Applicants then argue that sequencing involves detecting specific colors at specific locations in a sequencing gel. In response, this argument is non-persuasive because sequencing gel practice was well known at the time of filing of the instant application to be performed with radioactive labeling via a single label type and not via the detection of specific colors at specific locations in a sequencing gel. This well known practice of sequence labeling has not been instantly described as filed to be performed in any other way. No disclosure as instantly filed links the karyotyping different color practice to any other of the many techniques in the instant disclosure as filed. No other arguments have been set forth. Claims 1723, 1724, 1740, and 1741 yet contain this NEW MATTER. Also, newly added claim 1796 contains the above summarized NEW MATTER and is rejected as necessitated by amendment.

VAGUENESS AND INDEFINITENESS

Claims 1436-1439 and 1441-1444 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1436, lines 1-2, the phrase "said nucleotide structure or nucleotide analog structure (i)" is set forth without clear antecedent basis. It is noted that claim 1436 depends from claim 1432. Consideration of claim 1432 reveals that it does not provide antecedent basis for the above phrase. Claim 1432 depends from claim 1430 which also lacks providing antecedent basis for said above phrase. Claim 1430, in turn, depends from claim 1411. Consideration of claim 1411 also fails to provide any nucleotide structure or nucleotide analog structure as antecedent basis for the above cited phrase. Also claim 1411 contains two citations of "(i)", neither of which are directed to any nucleotide structure or nucleotide analog structure. Clarification via clearer claim wording is requested. Claims 1437-1439 and 1441-1444 also contains such nucleotide... citations wherein the presence of these in the practice of claim 1411 from which they all ultimately depend is unclear regarding antecedent basis. This rejection is necessitated by amendment firstly introducing this issue in the amendment, filed 12/31/03, however, after the previous office action, mailed 7/1/03.

REQUEST FOR INTERFERENCE, FILED 9/28/04

The above noted request is presently being processed and will be addressed shortly in a separate communication.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Since the fee set forth in 37 CFR 1.17(r) for a first submission subsequent to a final rejection has been previously paid, applicant, under 37 CFR 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a second submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 41.20(b) were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 12, 2005

 5/15/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER